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NOTICE OF ALLOWANCE AND FEE(S) DUE

61278 7590 09/15/2008
MILLER, CANFIELD, PADDOCK AND STONE, PLC
277 SOUTH ROSE STREET
SUITE 5000

EXAMINER

HAMUD, FOZIA M

ART UNIT PAPER NUMBER

DATE MAILED: 09/15/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.			
10/802,540	03/16/2004	Blake Pepinsky	BII-008.02	4023			
TITLE OF INVENTION: POLYMER CONJUGATES OF INTERFERON BETA-1A AND USES							

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$0	\$1440	\$1440	12/15/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT, PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 1SI. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

KALAMAZOO, MI 49007

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FFE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

appropriate. All further indicated unless corrects maintenance fee notifica	form should be used to correspondence including ed below or directed off tions.	or transmitting t ng the Patent, ad nerwise in Block	vance or 1, by (a	ders and notification o) specifying a new cor	nt ma	aintenance fees wi ondence address;	and/or	nailed to the current (b) indicating a sepa	correspo rate "FE	ndence address as E ADDRESS" for
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)					Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.					
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KALAMAZOO.	, MI 49007									(Depositor's name)
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10/802,540	03/16/2004			Blake Pepinsky		-		BII-008.02		4023
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nonprovisional	NO	\$1440		\$0	_	\$1440		\$1440		12/15/2008
EXAM	EXAMINER ART UNIT		Γ	CLASS-SUBCLASS	┚					
HAMUD,	FOZIA M	1647		530-351000						
1. Change of correspondence address or indication of "Fee Address" (37 CFR J.563). Change of correspondence address for Change of Correspondence Address form PTO/SB/122) anached. The Address from PTO/SB/122) anached. The Address' indication for "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Yumber is required. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON.				or agents OR, alterno (2) the name of a sin registered attorney of 2 registered patent a listed, no name will	the names of up to 3 registered patent attorneys agents OR, alternatively, the name of a single firm (having as a member a glistered attorney or agent) and the mannes of up to gestered attorney or agent) and the names of up to gestered patent aboracys or agents. If no name is 3					
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4a. The following fee(s) are submitted: Issue Fee Publication Fee (No small entity discount permitted) Advance Order - # of Copies			40	49. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) A check is enclosed. Payment by credit card. Form PTO-2038 is attached. The Director is brerby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number (enclose an extra copy of this form).						
	s SMALL ENTITY state	as. See 37 CFR I.		b. Applicant is no l						
NOTE: The Issue Fee an interest as shown by the	d Publication Fee (if req records of the United Sta	uired) will not be ites Patent and Tr	accepted ademark	I from anyone other tha Office.	ın th	e applicant; a regis	tered a	ttorney or agent; or th	e assigne	e or other party in
Authorized Signature					Date					
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MILLER, CANF	TELD, PADDOCK A	HAMUD, FOZIA M			
277 SOUTH ROSE	E STREET		ART UNIT	PAPER NUMBER	
SUITE 5000 KALAMAZOO, M	II 49007	1647 DATE MAILED: 09/15/2008			

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 502 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 502 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.	Applicant(s)			
10/802,540	PEPINSKY ET AL.			
Examiner	Art Unit			
FOZIA M. HAMUD	1647			

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address-All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant See 37 CFR 1313 and MPEP 1308.

- This communication is responsive to the response of 05/29/2008.
- The allowed claim(s) is/are 41-57, 60, 62-71, (now renumbered 1-28, respectively).
- 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of the:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____
 - Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- 5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date _____.
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1. Notice of References Cited (PTO-892)
- 2.
 Notice of Draftperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 05/29/2008
- Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. ☐ Notice of Informal Patent Application
- Interview Summary (PTO-413), Paper No./Mail Date
- 7. X Examiner's Amendment/Comment
- 8.

 Examiner's Statement of Reasons for Allowance
- 9. 🔲 Other _____.

Application/Control Number: 10/802,540

Art Unit: 1647

RCE:

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under Ex Parte Quayle, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submissions filed on 29 May 2008 has been entered.

Information Disclosure Statement:

 The information disclosure statements filed on 29 May 2008 has been received and complies with the provisions of 37 CFR §1.97 and §1.98. The information referred to therein has been considered as to the merits.

Prior Art:

 The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Runkel et al, Pharmaceutical Research 1998, Vol. 15, No. 4, pages 641-649. Kita et al, Drug Design and Delivery 1990, Vol. 6, pages 157-167.

Runkel et al teach that interferon beta 1a, (glycosylated form) displays 10 fold higher antiviral activity than interferon beta 1b, (non-glycosylated form) and that this is due to a stabilizing role of the carbohydrates, (see abstract, page 643, column 1 and table 1).

Kita et al teach that interferon gamma conjugated with polyethylene glycol at the N-terminus, (PEG-IFN-γ) displays comparable antiviral activity with the unmodified IFN-γ, (see abstract and page 163).

The instant invention discloses unexpectedly that PEG-IFN- β -1a displays a much higher antiviral activity than unmodified IFN- β -1a, (see figure 9).

Examiner's Amendment:

4. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the Issue Fee.

Authorization for this examiner's amendment was given in a telephone interview with Herald H. Fox, (Applicants' Representative) on 26 August 2008.

The application has been amended as follows:

IN THE CLAIMS:

Please amend claims as follows:

- Claim 45, (Twice amended), in line 2, before "amino acid sequence", delete "an"
- 4b. Claims 45 and 49, (Twice amended), in line 3, after "SEQ", insert ---ID---

Status of Claims:

 Claims 1-40, 58, 59 and 61 have been canceled. Claims 41-57, 60, 62-71 (now renumbered 1-28, respectively) are allowed.

Advisory Information:

Application/Control Number: 10/802,540

Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FOZIA M. HAMUD whose telephone number is (571)272-0884. The examiner can normally be reached on Monday-Friday: 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud Patent Examiner Art Unit 1647 25 August 2008

> /Bridget E Bunner/ Primary Examiner, Art Unit 1647